

REMARKS

This is in response to the 24 July 2008 office action.

Withdrawn claims 1-22 remain canceled without prejudice or disclaimer of the subject matter therein. Applicant reserves the right to file a continuing application including the subject matter of the canceled claims.

The 35 U.S.C. 112, first paragraph, rejection.

Claim 29 stands rejected under 35 U.S.C. 112, first paragraph. The office action states

[c]laim 29 recites the limitation ‘the hollow cap **encapsulates substantially all** of the bone instrumentation which projects from the bone.’ There is no disclosure or inherency as originally filed that the hollow cap encapsulates substantially all of the bone instrumentation which projects from the bone. (Office action at page 3.)

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent application with information known in the art and without undue experimentation.¹ The law does not require an applicant to describe in his specification every conceivable embodiment of the invention.²

Applicant’s disclosure includes ample description of a “hollow cap” that “encapsulates substantially all of the bone instrumentation which projects from the bone.” For example, applicant’s specification at page 2, first paragraph states “[i]n accordance with the present invention, a bone instrumentation cover or shield comprises a cap or casing which is dimensioned to be placed over and to encapsulate projecting parts of instrumentation installed in a bone....” Also, at page 4, last paragraph it states, in part, “[t]he cover casing 10 is designed and dimensioned to encapsulate the projecting parts to prevent irritation or injury.” Applicant’s drawing shows hollow cap 10, 20, 30, 40 and 50 that surrounds the bone instrumentation which projects from the bone. One of ordinary skill in the art would have understood the disclosed hollow cap structure accomplishes encapsulation of the bone instrumentation which projects from the bone as disclosed in the specification. The importance of protecting the tissue from the bone instrumentation is discussed in the specification such that encapsulation of a portion or of

¹ See U.S. v. Electronics Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed Cir. 1988).

² Id. citing Hybritech Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert denied, 107 S.Ct. 1606 (1987).

substantially all of the bone instrumentation would be understood by one of ordinary skill in the art. The office action does not provide any reasons or explanation why one of ordinary skill in the art being aware of the disclosed bone instrumentation encapsulation process would not have been aware of the importance of encapsulating either a portion or substantially all of the bone instrumentation which projects from the bone. The office action omits this important explanation. For at least these reasons, withdrawal of this rejection is respectfully requested.

The 35 U.S.C. 112, second paragraph, rejection.

Claims 26-28 and 34 stand rejected under 35 U.S.C. 112, second paragraph. The terminology “a second suture string” in claim 26 is asserted to be not appreciably different from the “plurality of first suture strings” as recited in claim 25. It is urged that it is unclear whether the second and first suture strings have the same properties. Claim 34 is rejected in that “said hollow cap or casing” does not have a proper antecedent.

A decision as to claim indefiniteness requires a determination of whether those skilled in the art would understand what is claimed.³ 112, 2d Claims are considered to satisfy the requirements in the second paragraph of 112 if they define the metes and bounds of the claimed subject matter with a reasonable degree of precision and particularity.⁴

Applicant’s disclosure at page 6, last paragraph, describes “adjustable suture strings 46a tied to the lower edge of the cap portion 40” and explains “the loose ends of the adjustable suture strings are pulled through the cinch ring openings 42a to tighten the cap vertically down onto the instrumentation.” “Two suture strings 46b on opposite sides of the cap have ends that are attached to the cinch ring and are not adjustable, as their function is to tie the cinch ring to the cap portion so that it does not slip away from the cap and adjustable sutures while being handled” is also described. Thus, two different types of suture strings are disclosed. In claim 25 the first suture strings have a first end fixedly secured to the cap and a second end threaded through the cinch ring for tightening the cap to the ring. In claim 26 the second suture strings have a first end coupled to an edge of the cap and a second end coupled to the cinch ring. The distinction between the first and second suture strings is thus clear in the claims and supported in the disclosure. Withdrawal of the rejection of claims 26-28 is respectfully requested.

³ See *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991).

⁴ See *In re Venezia*, 530 F.2d 956, 958, 189 USPQ 149, 151 (CCPA 1976) and *In re Hammack*, 427 F.2d 1378, 166 USPQ 204 (CCPA 1970).

The phrase “or casing” in claim 34 has been deleted to overcome the rejection of claim 34. The examiner’s noting of the omission of an antecedent for this phrase is appreciated.

The 35 U.S.C. 101 rejection.

Claims 23-34, 38 and 39 stand rejected under 35 U.S.C. 101 as directed to non-statutory subject matter. The office action urges “applicant cannot positively recite a portion of the human body... applicant has positively recited the cover being installed over bone instrumentation which has been placed with bone.” The office action points out that claim 36 is not subject to this rejection as it is directed to “a bone instrumentation cover capable of being placed over bone instrumentation during bone repair...” The preamble of independent claims 23 and 30 has been amended to conform to the acceptable language of claim 36. On this basis, withdrawal of the rejection of claims 23-34, 38 and 39 is respectfully requested.

The 35 U.S.C. 102(b) rejection.

Claims 23-34, 36, 38 and 39 stand rejected under 35 U.S.C. 102(b) as anticipated by Ellman (U.S. Patent No. 4,428,375).

To support a rejection of a claim under 35 U.S.C. 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference.⁵

Ellman discloses a bag 15 to compress an organ to assist in healing a fracture in the organ. Ellman discloses “bag 15 has a mesh or network construction” (column 2, line 32). The mesh has openings 19. Ellman states that “another advantage is that the multiple interstices or openings in the net allows ingrowth of tissue through the net openings and around the net solid parts and thus enhances healing.” (Column 3, lines 55-58.)

Applicant’s disclosure states “[t]he shield or cover preferably is in the form of a solid rectangle or solid oval or other suitable shape and closely fits onto the instrumentation in a manner analogous to an armrest cover on the arm of a chair.... The shield or cover **prevents ingrowth** of bone or fibrous tissue into interstices of the instrumentation because it **provides a mechanical barrier to such intrusion.**” (Emphasis added.) Applicant’s claim 23 recites a cap “adapted to provide a medically safe physical barrier between the part of the bone

⁵ See *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984).

instrumentation and the surrounding bone and soft tissue....” Applicant’s claim 30 similarly requires “the hollow cap being adapted to separate the part of the pedicle screw from surrounding bone and soft tissue....” Applicant’s claim 36 requires “means... for providing a medically safe physical barrier between the part of the bone instrumentation and the surrounding bone and soft tissue.” Ellman’s bag 15 does not and cannot prevent “ingrowth of bone or fibrous tissue” because the bag 15 has holes in the bag 15 (i.e., a mesh has holes or openings which as disclosed in Ellman permit ingrowth). Ellman’s bag 15 does not provide “a medically safe physical barrier between the part of the bone instrumentation and the surrounding bone and soft tissue” (as recited in applicant’s claims 23 and 36) and does not “separate the part of the pedicle screw from surrounding bone and soft tissue” (applicant’s claim 30). The above remarks demonstrate that Ellman actually teaches away from the claimed invention in that Ellman discloses the desirability of ingrowth whereas applicant’s claimed invention prevents ingrowth. One following the teaching of Ellman would be discouraged from following the path set out by applicant and would be led in a direction away from the invention provided by the applicant.

For at least these reasons, Ellman does not anticipate the invention of independent claims 23, 30 and 36 (and dependent claims 24-29, 31-34, 38 and 39).

New claims 40 and 41 have been added and avoid the prior art of record.

Conclusion.

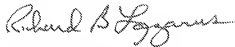
For all of the above reasons claims 23-41 appear to be in condition for allowance and such is respectfully requested.

If there is any issue remaining to be resolved, the examiner is invited to telephone the undersigned so that resolution can be promptly effected.

It is requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response with the fee for such extensions and shortages in other fees, being charged, or any overpayment in fees being credited, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 (6714-46501).

Respectfully submitted,

BARNES & THORNBURG LLP

A handwritten signature in dark ink, appearing to read "Richard B. Lazarus", with a stylized flourish at the end.

Richard B. Lazarus

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